DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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November 4, 2014

Renovis Surgical Technologies, Incorporated
% Sharyn Orton, Ph.D.
Senior Consultant
MEDIcept, Incorporated
200 Homer Avenue
Ashland, Massachusetts 01721

Re: K141676
Trade/Device Name: Renovis Surgical Porous Acetabular Cup System
Regulation Number: 21 CFR 888.3358
Regulation Name: Hip joint metal/polymer/metal semi-constrained porous-coated uncemented prosthesis
Regulatory Class: Class II
Product Code: LPH
Dated: September 30, 2014
Received: October 3, 2014

Dear Dr. Orton:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21

CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Lori A. Wiggins -S

for
Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K141676

Device Name
Renovis Surgical Porous Acetabular Cup System

Indications for Use *(Describe)*
The Renovis Surgical Hip Replacement System is indicated for patients suffering from:
1. Non-inflammatory degenerative joint disease including osteoarthritis and avascular necrosis;
2. Rheumatoid arthritis;
3. Correction of functional deformity;
4. Treatment of non-union, femoral neck fracture and trochanteric fractures of the proximal femur with head involvement, unmanageable using other techniques; and
5. Revision procedures where other treatment or devices have failed.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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RENOVIS

Traditional 510(k) Summary
as required by 21 CFR 807.92(a)
K141676

A) Submitted by: Renovis Surgical Technologies Inc.
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Official Contact: Anthony DeBenedictis
Vice President of Quality Assurance

Consultant: Sharyn Orton, Ph.D.
MEDIcept, Inc.
200 Homer Ave
Ashland, MA 01721

Date prepared: September 25, 2014

B) Device Name: Prosthesis, hip, semi-constrained, metal/polymer, porous uncemented

Common Name: Total Hip Arthroplasty – Acetabular Components

Proprietary Name: Renovis Surgical Porous Acetabular Cup System

Device Class: Class II

Regulation number: 21 CFR 888.3358

Regulation name: Hip joint metal/polymer/metal semi-constrained porous-coated uncemented prosthesis

Product code: LPH

Classification panel: Orthopedic

C) Predicates:

K112897	Renovis A400 Surgical Hip Joint Replacement System (acetabular shells)
K132312	Renovis Tesera Trabecular Technology (T^3) Acetabular Shell System
K974093	Encore Orthopedics Foundation Porous Coated Hemispherical Acetabular Cup

D) Device Description:

The Renovis Porous Acetabular Cup System ("Porous shell") are titanium, hemispherical cups consisting of varying sizes (outer diameter of 44 – 66 mm) and screw hole options (no hole shell and cluster hole shells) to accommodate patient anatomy and/or surgical technique. Instrumentation is provided with the system.

The Renovis Porous Acetabular Cup System is part of the Renovis Surgical Hip Replacement System and is to be used with Renovis Surgical Hip Replacement System acetabular and femoral components.

The Renovis Surgical Porous Cup System complies with the following material standards:

- ASTM F136-13 Standard Specification for Wrought Titanium-6Aluminum-4Vanadium ELI (Extra Low Interstitial) Alloy for Surgical Implant Applications (UNS R56401) or
- ASTM F620-11 Standard Specification for Titanium Alloy Forgings for Surgical Implants in the Alpha Plus Beta Condition
- ASTM F67-13 Standard Specification for Unalloyed Titanium, for Surgical Implant Applications (UNS R50250, UNS R50400, UNS R50550 and UNS R50700)
- ASTM A564-13 Standard Specification for Hot-Rolled and Cold-Finished Age-Hardening Stainless Steel Bars and Shapes

E) Indications For Use:

The Renovis Surgical Hip Replacement System is indicated for patients suffering from:

1. Non-inflammatory degenerative joint disease including osteoarthritis and avascular necrosis;
2. Rheumatoid arthritis;
3. Correction of functional deformity;
4. Treatment of non-union, femoral neck fracture and trochanteric fractures of the proximal femur with head involvement, unmanageable using other techniques; and
5. Revision procedures where other treatment or devices have failed.

F) Substantial Equivalence Comparison and Discussion

The Renovis Surgical Porous Acetabular Cup System has similar Indications for Use, operating principle and basic design, sizes and geometries, biocompatible materials, and is offered gamma sterilized, like the predicate devices. The manufacturing processes used for the outer coating differ between the Renovis Surgical Porous Acetabular Cup System and two of the predicate devices. The Renovis Surgical Porous Acetabular Cup System meets the coating characterization criteria in 21 CFR 888.3358, and expected performance testing. The Renovis Surgical Porous Acetabular Cup System is substantially equivalent to the predicate devices.

G) Performance Testing - Bench

Performance testing was successfully completed.

The Renovis Surgical Porous Acetabular Cup System complies with:

- 21 CFR 888.3358
- FDA "Guidance Document for Testing Orthopedic Implants with Modified Metallic Surfaces Apposing Bone or Bone Cement", April 8, 1994
- ASTM F1854-09 Standard Test Method for Stereological Evaluation of Porous Coatings on Medical Implants
- ASTM F1472-08e1 Standard Specification for Wrought Titanium-6Aluminum-4Vanadium Alloy for Surgical Implant Applications (UNS R56400)
- ASTM F1044-05 (2011) Standard Test Method for Shear Testing of Calcium Phosphate Coatings and Metallic Coatings
- ASTM F1147-05 (2011) Standard Test Method for Tension Testing of Calcium Phosphate and Metallic Coatings
- ASTM F1820-97:2009 Standard Test Method for Determining the Forces for Disassembly of Modular Acetabular Devices

Sterilization, shelf life, packaging and shipping validation studies have been conducted. The Renovis Surgical Porous Acetabular Cup System complies with:

- ISO 11137-2:2013 Sterilization of health care products -- Radiation -- Part 2: Establishing the sterilization dose
- ASTM F1980-07 (reapproved 2011) Standard Guide for Accelerated Aging of Sterile Barrier Systems for Medical Devices
- ISO 11607-2:2009: Packaging for terminally sterilized medical devices – Part 2: Validation requirements for forming, sealing and assembly processes
- ISTA 2A Partial Simulation Performance Tests; Packaged-Products weighing 150 lb (68 kg) or Less
- ASTM D4169-09: Standard Practice for Performance Testing of Shipping Containers and Systems

Conclusion

Renovis Surgical Porous Acetabular Cup System is substantially equivalent to the predicate devices, and does not raise new issues of safety or effectiveness.

H) Other Standards

- ASTM F983-86 (Reapproved 2013) Standard Practice for Permanent Marking of Orthopaedic Implant Components
- ASTM F565-04 (Reapproved 2013) Standard Practice for Care and Handling of Orthopedic Implants and Instruments